Life-Assist
Helping Heroes Save Lives

URGENT MEDICAL DEVICE RECALL

Tuesday, March 7, 2017

Dear Valued Life-Assist Customer,

According to our records you may have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have the following product(s), with any of the affected lot numbers in your possession.

Covidien Curity™ Eye Pad Oval & Curity™ Saline Dressing

Life-Assist, Inc. Product No.	Product Description	Covidien Product No.	Lot Number beginning with
BA2841	CURITY™ Eye Pad Oval	2841	12, 13, 14, 15, 16
KEND_3606	CURITY™ Saline Dressing, 4"x 8"	3606	14, 15, 16 (Excludes lots 16J098062, 16J098162, 16J098262)

******BA2841, CURITY™ Eye Pad Oval is a component in several Life-Assist stock and custom built kits.**

Please be sure to thoroughly inspect the following kits for affected product lots:

Life-Assist Kit No.	Product Description	BA2841 Qty (EA)
BU020A	SISKIYOU BURN KIT™	6
BU030C	BURN FREE™ Burn Kit	2
FJ8000	Emergency First Aid Kit	2
KIT69	Responder II Kit™	2
KIT77-BLU	Deluxe First Response Trauma Kit™, Navy Blue	4
KIT77-ORG	Deluxe First Response Trauma Kit™, Orange	4
KIT4900-BLU	KINGS™ Trauma Kit, Navy Blue	4
KIT4900-RED	KINGS™ Trauma Kit, Red	4
KIT5025-ORG	First Response Trauma Kit™, Orange	2
KITS_BU020-CDF5	Burn Kit, CDF Specs w/ Sodium Chloride	4
KITS_BU020-CDF6	Burn Kit, CDF Specs w/ Sterile water	4
KITS_BU-CDF-CONTENTS	BURN KIT, CDF SPECS, W/STERILE WATER, (contents only)	4
KITS_FIRSTAID-AMADOR	First Aid Kit, Metal Box, Custom	2
KITS_KIT66LR-RED	Longbow Ranger Trauma Kit, Red	4
KITS_KIT69CONTENTS	KIT69 (contents only)	2
KITS_KIT77A	KIT, TRAUMA (contents only)	4
KITS_KIT77-UP	Deluxe First Response Trauma Kit™, Universal Precautions	4

11277 Sunrise Park Drive
Rancho Cordova, CA 95742
(800) 824-6016 Phone
(800) 290-9794 Fax
customerservice@life-assist.com
www.life-assist.com

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continued…

Life-Assist Kit No.	Product Description	BA2841 Qty (EA)
KITS_KIT999-BLU	KIT, TRAUMA, ALPHA PAK LARGE, BLUE	4
KITS_KIT5025-CUSTOM	First Response Trauma Kit™, Orange	2
KITS_LACOFD	KIT, TRAUMA, LACoFD	2
KITS_PERMANENTE	Kit, Custom, Doctor	4
KITS_PGEKIT4	TRAUMA KIT, PG & E SPECS, FS950P-BLU	2
KITS_TRAUMA-SMUD	KIT, TRAUMA, RED	4

Reason for Recall: Medtronic is voluntarily recalling specific item codes and production lots of Covidien Curity™ & Kerlix™ products due to the potential for the sterile packaging to be compromised.

The distribution date range of the affected lots is February 2011 to November 2016 on BA2841 and February 2014 to December 2016 on KEND_3606.

Action Required:

1. Please forward this notification to any individual in your organization who may use or be in possession of affected products.

2. Complete and return the **RECALL PRODUCT RETURN FORM** as instructed in the enclosed manufacturer recall notification, naming Life-Assist, Inc. as the Distributor.

3. Contact Life-Assist Customer Service Department at 800-824-6016 or salesservice@life-assist.com for Return Authorization and/or to place your replacement order.

4. Return affected lots to Life-Assist, Inc. 11277 Sunrise Park Drive, Rancho Cordova, CA 95742, with a copy of the completed **RECALL PRODUCT RETURN FORM**.

5. Medtronic will issue credits for returns to Life-Assist and they will be applied customer accounts accordingly.

As always, please contact Life-Assist, Inc. Customer Service Department at 800-824-6016 or salesservice@life-assist.com with any questions or concerns.

We apologize for any inconvenience.

Medtronic
60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

URGENT MEDICAL DEVICE RECALL

Covidien Curity™ Eye Pad, Curity™ Eye Pad Oval, Kerlix™ Super Sponge Saline Dressing, Curity™ Wet Dressing, Curity™ Sodium Chloride Dressing and Curity™ Saline Dressing

March 3, 2017

Attention: Risk Management Director and O.R. Materials Management
Distributors of affected product

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing. This voluntary recall is being conducted due to the potential for the sterile packaging to be compromised. The use of products with this condition may result in a potentially increased risk for infection. There have been no reports of infection associated with this issue.

Medtronic requests that you quarantine and return any unused products of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below.

Item Code	Item Description	Lot Number beginning with	Expiration Date
03201	Covidien Curity™ Eye Pad	12, 13, 14, 15, 16	From 2017-02 through 2021-11
2841	Covidien Curity™ Eye Pad Oval		
91650	Covidien Curity™ Eye Pad		
3337	Covidien Curity™ Wet Dressing	14, 15, 16 *Exclude lots 16J098062 16J098162 16J098262	From 2017-02 through 2019-11
3338	Covidien Kerlix™ Super Sponge Saline Dressing		
3339	Covidien Curity™ Sodium Chloride Dressing		
3606*	Covidien Curity™ Saline Dressing		

If you have distributed the sterile Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline Dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing products listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

This voluntary recall affects only the item codes and lots listed above.

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This action is being taken with the knowledge of the FDA and other regulatory authorities. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Post Market Vigilance at: Mansfield.productmonitoring@Covidien.com

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail)
- Call FDA 1-800-332-1088

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed above.

2. Please return affected product as follows:

	Customer with inventory:	Customer with Zero Inventory	Where to send the completed form
Purchased **DIRECTLY** from Medtronic	Ship affected product with RGA# provided by Customer Service (800) 882-5878) to: **Medtronic Attn: Field Returns Department 195 McDermott Road North Haven, CT 06473 USA**	Complete form and check the box indicating "no inventory".	Fax form to 800-895-6140 or email it to Feedback.customerservice@Covidien.com **Exception:** Customers with Zero inventory, Fax to (203) 492-7719 or email to FCAMITG@Covidien.com
Purchased from a **Distributor**	Complete **ALL** fields on the form and contact your Distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory".	Fax form to 203-492-7719 or email to FCAMITG@Covidien.com

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service at (800) 882-5878.

Sincerely,

Subu Mangipudi
Vice President, Quality
Patient Monitoring and Recovery
Medtronic

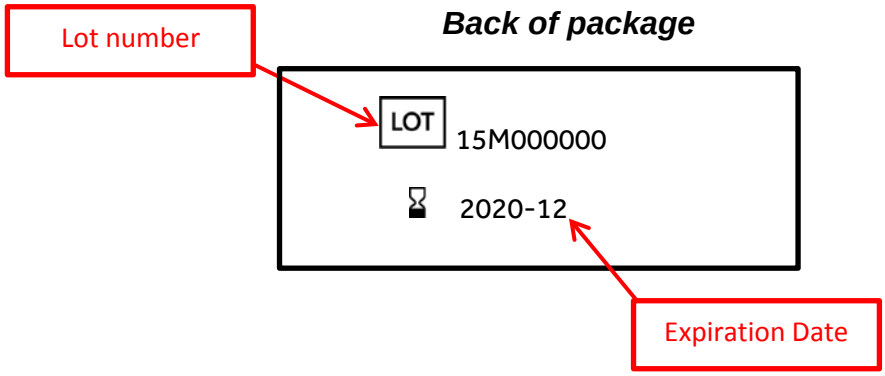
Medtronic

Attachment A

Distinguish affected product by Item Code and Lot Number.

Front of package

Back of package



Medtronic

RECALLED PRODUCT RETURN FORM

Covidien Curity™ Eye Pad, Curity™ Eye Pad Oval, Kerlix™ Super Sponge Saline Dressing, Curity™ Wet Dressing, Curity™ Sodium Chloride Dressing and Curity™ Saline Dressing

PLEASE COMPLETE THIS FORM

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):** X

A. Direct Customers:

Account Name:

Primary Account #:

Account Address:

City:

State: Zip Code:

B. From a Distributor:

Distributor: Life-Assist, Inc.

Customer Information:

Customer Name:

Address:

City:

State: Zip:

~~RETURN INVENTORY TO: Medtronic, Attn: Field Returns Dept., 195 McDermott Road, North Haven, CT 06473 USA~~

Return Goods Authorization (RGA) #: contact Life-Assist for RA ~~(please include once received from Customer Service)~~

No Inventory (Please check):

Item Code	Lot Number	Qty	Case or Each

I acknowledge receipt of the Covidien Curity™ eye pad, Curity™ eye pad oval, Kerlix™ super sponge saline dressing, Curity™ wet dressing, Curity™ sodium chloride dressing and Curity™ saline dressing

* (Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

~~**Product purchased directly from Medtronic:** feedback.customerservice@Covidien.com or fax to (800)-895-6140.~~

Product purchased through distributor: FCAMITG@Covidien.com or fax it to (203) 492-7719.